

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

HERAEUS MEDICAL GMBH, Plaintiff, v. ESSCHEM, INC., Defendant.	: : : : : : :	CIVIL ACTION NO. 14-5169
--	---------------------------------	---------------------------------

Memorandum Opinion

Rufe, J.

November 3, 2014

Hereaus Medical GMBH, a German company specializing in the development and production of bone cement, filed this action alleging that Esschem, Inc. is producing and selling two copolymers, R262 and R263, which were developed using Heraeus’s misappropriated trade secrets, to Heraeus’s competitor, Biomet, for use in Biomet’s bone cements. Presently before the Court is Heraeus’s motion for a temporary restraining order (“TRO”). Heraeus asks the Court to enjoin Esschem from producing and selling R262 and R263 until expedited discovery and a preliminary injunction hearing are completed. The Court held a hearing on this motion, at which counsel for both parties presented arguments, and allowed the parties to fully brief the issues and present declarations in support of their positions.

Factual Background¹

Heraeus is a developer and producer of bone cement used in hip and knee replacements. In 1959, Heraeus introduced a bone cement called Palacos, which was developed after decades of research and development. It continues to sell this product, as well as other bone cement

¹ The facts recited in this section are taken from the Complaint, facts asserted at the hearing, the First and Second Declaration of Dr. Friedrich Klinkert [Doc. No. 5, Exh. 2; Doc. No. 14, Exh. B], the Declaration of Karl-Wilhelm Schneider [Doc. No. 5, Exh. 1], the Declaration of Dr. Wolfgang Witz [Doc. No. 39, Ex. B], the Declaration of Judy Fenton [Doc. No. 39, Exh. C], and the June 5, 2014, Judgment of the German Court of Appeals [Doc. No. 5, Exh. B and Doc. No.39, Exh. A]. The Court recognizes that some of these facts may be contested at a later stage in the litigation, and the Court’s recitation of facts on this application for a TRO does not represent an adjudication of the facts or claims on the merits. *See Wright and Miller, Federal Practice and Procedure* § 2951.

products. In 1972, Heraeus entered into a bone cement distribution agreement with Merck. Heraeus was required by law and the agreement to provide Merck with its confidential information and trade secrets, so that Merck could obtain regulatory approval for the bone cement products and distribute them in the United States and elsewhere. Under the terms of the agreement, Merck was required to protect Heraeus's confidential information and trade secrets, and not misappropriate them or provide them to third parties. Heraeus and Merck also entered into an agreement to research and develop a new bone cement product to be used in a new vacuum application system (VacPac) being developed by Biomet.

In 1997, Merck entered into a joint venture with Biomet. Heraeus agreed to supply bone cement products to the Merck/Biomet joint venture. However, in Spring 2004, Merck sold its interest in the joint venture to Biomet without informing Heraeus. This sale of its joint venture interest transferred Merck's interest in the distribution of Heraeus's bone cement products to Biomet. Biomet thus obtained Heraeus's confidential information and trade secrets without Heraeus's consent. In February 2005, Heraeus advised Biomet that it would stop supplying Biomet with its bone cement products as of August 31, 2005.

Shortly after this notice was provided, Biomet sued Heraeus, seeking to compel it to continue supplying Biomet with bone cement products. According to a declaration prepared for that suit by Biomet witness Dr. Sprecht (a former Merck employee who began working for Biomet), the lawsuit was necessary because there were no viable alternative bone cement products available in the market, and Biomet would not be able to develop its own equivalent bone cement for at least two years. A few months later, Biomet announced that it had produced its own comparable bone cement and dropped the lawsuit.

In 2004, around the time Merck sold its interest in the Merck-Biomet joint venture to Biomet, Biomet contracted with Esschem, a Pennsylvania company which manufactures and

distributes acrylic polymers and other compounds which are ingredients used to make bone cement products, and asked Esschem to develop and produce certain copolymers it needed to manufacture its own bone cement. Biomet, through Dr. Sprecht (who had access to Heraeus's trade secrets, but was subject to the confidentiality obligations and restrictions of the companies' agreement) participated in the development of these copolymers. It is alleged that Biomet provided Heraeus's trade secrets and confidential information to Esschem, which used this information to develop copolymers R262 and R263 for Biomet's new bone cement.

In August 2005, Biomet launched a line of bone cements which directly compete with Heraeus's products, and which are virtually identical to Heraeus's products in chemical identity, molecular weight, particle size distribution, and other characteristics. After dominating the bone cement market for 50 years, Heraeus began losing market share, ultimately losing half of its previous market share.

When Heraeus learned that its regulatory files had been transferred to Biomet by Merck, it suspected that Biomet had used Heraeus's confidential information to develop its competing products. Heraeus obtained and tested samples of Biomet products, and found they were virtually identical to Heraeus's products, except for minor discrepancies. In 2008, Heraeus sued Biomet and its affiliates in the German court system, alleging that Biomet had misappropriated its trade secrets and confidential information. Esschem was not named as a defendant in the German litigation, but was the target of discovery litigation related to the German suit, filed before this Court in 2009.²

On June 5, 2014, the Frankfurt Court of Appeals in Germany reversed a ruling of the lower court and entered judgment in favor of Heraeus, finding that Biomet used three technical specifications which were Heraeus's trade secrets, and which Biomet knew were trade secrets, to

² *Heraeus Kulzer GmbH v. Esschem, Inc.*, 09-mc-17.

guide Esschem in developing copolymers for use in Biomet's bone cement. The court enjoined Biomet from manufacturing, offering, or distributing bone cement products which use Heraeus's trade secrets, including those containing Esschem's copolymers R262 and R263. Heraeus alleges that, despite the German court order, Biomet continues to buy R262 and R263 from Esschem and to sell bone cement developed using Heraeus's trade secrets outside of Germany. Both parties have appealed the ruling of the Frankfurt Court of Appeals.³

Heraeus filed the present lawsuit on September 8, 2014, alleging that Esschem knew or should have known that the information and guidance supplied by Biomet relied upon Heraeus's trade secrets, and asserting claims for misappropriation of trade secrets under Pennsylvania's Uniform Trade Secrets Act, conspiracy to misappropriate trade secrets, unjust enrichment, unfair competition, tortious interference with economic advantage, and conversion. Heraeus filed a Motion for Preliminary Injunction on September 10, 2014, but, when counsel for Esschem did not immediately enter their appearance after Esschem was served, Heraeus filed the Motion for a TRO on September 22, 2014.

Discussion

Heraeus seeks a TRO enjoining Esschem from directly or indirectly using, disclosing, or retaining trade secret information belonging to Heraeus, including the specifications and formulas used to make Esschem's R262 and R263 copolymers. Heraeus also seeks an accounting and return of all proprietary information in Esschem's possession, and an accounting of all proprietary information disclosed to third parties.

A TRO is an extraordinary form of relief, designed to temporarily maintain the status quo (generally for 14 days, and on rare occasions for longer) while the parties prepare to litigate the

³ Heraeus has also filed a declaratory judgment action and an enforcement action in the German district court, seeking rulings that the injunction imposed by the Frankfurt Court of Appeals extends beyond Germany.

issues on a motion for a preliminary injunction. A TRO order may be appropriate where the movant has made reasonable efforts to provide notice,⁴ and demonstrated (1) a likelihood of success on the merits; (2) the likelihood of irreparable harm to the movant if the motion is not granted; (3) granting the relief sought will not result in greater harm to the non-moving party; and (4) the public interest favors such relief.⁵

The Status Quo

“A primary purpose of [a TRO or] a preliminary injunction is maintenance of the status quo until a decision on the merits of a case is rendered.⁶ A motion for a TRO should be denied if the injunction sought would fundamentally alter the status quo.⁷ It is undisputed that Esschem has been producing R262 and R263 and selling these copolymers to Biomet for at least nine years. Biomet has sold its bone cements containing R262 and R263 for at least nine years, and has a significant market share. Thus, in asking the Court to enter this TRO enjoining Esschem from producing and selling R262 and R263, it is asking the Court not to maintain the status quo, but to revert back to the way things were nine or more years ago, before Esschem developed R262 and R263.

The Risk of Irreparable Harm

The Court is not persuaded that the extraordinary, emergency relief sought is appropriate, given the facts of this case. In support of its motion, Heraeus argues that it will suffer additional irreparable harm if the TRO is not granted, because Biomet continues to sell its bone cements in Europe (as it has for over nine years), despite the German court judgment against Biomet.

⁴ Adequate notice has been provided. Plaintiff served the summons and complaint on Defendant, and provided actual oral and written notice of this motion for a TRO to Defendant in advance of the hearing. Defendant is represented by counsel, who appeared and argued at a hearing on the motion for a TRO, and who filed briefs in opposition to the motion after the hearing.

⁵ *Bimbo Bakeries USA, Inc. v. Botticella*, 613 F.3d 102 (3d Cir. 2010).

⁶ *Acierno v. New Castle County*, 40 F.3d 645, 647 (3d Cir. 1994).

⁷ *Id.*

Heraeus asserts that it set the gold standard for bone cement in the market for decades, with products it developed after years of research, and until Biomet announced its bone cement product line in 2005, it had no strong competitors. Heraeus asserts that it has lost 50% of its market share in Europe since Biomet began selling competing products using Defendant's copolymers in 2005. Heraeus argues that the competitive disadvantage created by the availability of Biomet's products using Esschem's R262 and R263 would be difficult to quantify for purposes of calculating damages if the Court does not enter a TRO and it prevails at trial.

While the Court accepts, for purposes of this motion, that Heraeus has lost significant market share over the *nine years* Biomet's competing bone cements have been on the market, Heraeus has put forth no evidence that its market share would continue to decline in any meaningful, yet difficult to quantify, way over the weeks (or even months) it will take to litigate a motion for a preliminary injunction.⁸ Thus, the Court cannot conclude that Heraeus faces the probability of immediate and irreparable harm if Esschem is not immediately enjoined from producing and selling its copolymers.

The Public Interest

As Heraeus has not demonstrated a probability of immediate and irreparable harm, the Court need not reach the other relevant factors. However, the Court notes that the public interest factor also weighs in favor of denying the TRO. The Court acknowledges that the public has a strong interest in protecting intellectual property rights, and laws such as the Pennsylvania Uniform Trade Secrets Act encourage product development and innovation by protecting intellectual property. However, this case involves bone cements which have been on the market for years, and Biomet enjoys a significant market share. Esschem has asserted that individual

⁸ See *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 92 (3d Cir. 1992) (holding that the District Court erred in granting a preliminary injunction where the immediate irreparable harm at issue was the further disclosure of a trade secret which had already been disclosed, as "a threat of disclosure may establish immediate irreparable harm but 'further' disclosure of something already revealed cannot.")

orthopedic doctors develop preferences for and experience with certain bone cements, which they use day in and day out in surgery.⁹ Yet, many hospitals do not stockpile bone cement, but rather order it on an as-needed basis, the day before or the day of the procedure.¹⁰ If a surgeon's preferred bone cement were to suddenly become unavailable, that surgeon would be required to substitute a different, less familiar product. Because Heraeus's and Biomet's bone cements differ in their working and setting time, the Court may infer that this could increase the risks of surgery.

In addition, Biomet is the market leader in the production of spacer molds (temporary implants), and the FDA has approved its spacer molds for use only with Biomet's own bone cement.¹¹ Biomet sells thousands of its spacer molds each year, and if the Court entered the requested TRO, the product effectively would become unavailable in the United States. Although other companies do make spacer molds, these companies control a much smaller market share and it is not certain that they would be able to meet the need.

Based on the limited record before the Court, these public interest concerns further tip the balance in favor of denying the TRO.

Other Considerations

In reaching this ruling, the Court notes as well that Heraeus has asked the Court to enter this TRO not on a very time limited basis (14 or 28 days), as is typical for a TRO, but on a longer-term basis, while the parties conduct discovery. In addition, the Court notes that Heraeus

⁹ Although Biomet and Heraeus's bone cements are equivalent in many ways, Esschem asserts that they differ in working time, setting time, color, texture, packaging, and other details. Declaration of Judy Fenton, Doc. No. 39, Exh. C.

¹⁰ *Id.*

¹¹ *Id.*

failed, in its TRO motion and at oral argument, to address the issue of a security bond to be posted with the Court.¹²

Conclusion

For all the above reasons, the Court declines to impose the TRO sought by Heraeus. An appropriate order follows.

¹² The posting of a bond likely would be mandatory, not discretionary, under Rule 65(c), if the Court were to grant the motion for TRO in this case. Heraeus addressed the issue of a security bond only briefly in its October 3, 2014 letter brief. In that correspondence, Heraeus asked the Court to require Esschem to provide evidence of the profits it expects it will lose if the TRO is entered, and if the Court determines a bond is appropriate. Because a TRO will not be entered, the Court need not address this issue.